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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,875	07/20/2005	Jonathan Rhodes	69155-2	1901

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EXAMINER
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ALONIS, MELENIE LEE

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,875	<b>Applicant(s)</b> RHODES, JONATHAN	
	<b>Examiner</b> Melenie Alonis	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 19-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 19-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-14 and 19-33 are presented for examination on the merits.

#### ***Claim Objections***

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-2, 12-21, 23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As drafted, claims drawn to a composition comprising soluble fiber derivable from fruit of the *Musa* spp. read on a product of nature (for example, as drafted-these claims read upon *Musa* fruit found in nature since they are naturally comprised of soluble dietary fiber).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and a method for treating Inflammatory Bowel Disease, does not reasonably provide enablement for a composition and a method for the prevention of Inflammatory Bowel Disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated that a composition comprising an effective amount of soluble fiber derived from a fruit of the *Musa* spp. is useful to treat Inflammatory Bowel Disease. However, these claims also encompass using the soluble fiber composition to prevent Inflammatory Bowel Disease, which is clearly beyond the scope of the disclosed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies, including preventing Inflammatory Bowel Disease, the cause of which is not well understood, as admitted by applicants and as cited by Campos et al. (see e.g. abstract).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 14, 19-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 6, 19, 24-26, are rendered vague and indefinite by the term "derivable". It is unclear whether the soluble fiber being referred to is actually derived from the source or method which follows the term or if the soluble fiber referred to is merely capable of being derived from such a source or method, but is not, in fact, derived from that source or method.

Claim 2 is rendered vague and indefinite by the term "decantable" in line 2. It is unclear if the aqueous solution is or is not decanted from homogenized fruit.

Claims 2, 8-9, 25 are rendered vague and indefinite by the term "fruit". It is unclear whether the fresh fruit being referred to is fruit from *Musa* or if some other fruit is being referred to.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 and 19-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fagbemi.

A composition and method for the prevention or treatment of Inflammatory Bowel Disease comprising a therapeutically effective amount of a soluble fiber derivable from fruit of the *Musa* spp. is claimed. Dependent claims include that the fiber is derivable from an aqueous solution decantable from homogenized fruit, that the fiber is derived from boiling the fruit, that the soluble fiber is treated to remove the starch, that the fiber is obtained by chopping fresh fruit and removing any skins and placing in an aqueous solution; or freeze drying whole fruit (excluding skins), milling it and placing in an aqueous solution; or milling desiccated fruit and placing it in an aqueous solution; or taking flour prepared from fruit and placing in an aqueous solution. Further dependent claims include nutritional/food products which contain the composition instantly claimed/disclosed.

Fagbemi teaches a composition (flour) obtained from plantains (*Musa paradisiaca*) as well as a method for obtaining the composition. Fagbemi disclosed that the flour is produced from plantains which were peeled, sliced, blanched at 100°C (boiling), drying, milling and further drying the fruit (see e.g. p. 262 para 2). Please note

that boiling the fruit serves to remove starch. The flour disclosed by Fagbemi would intrinsically be in the form of a powder. Fagbemi teaches that the flour contains 1.33-2.0g/100g of crude fiber (see e.g. table 1), which would intrinsically contain the soluble fiber instantly claimed. Fagbemi further teaches that the flour can be incorporated into food and beverage products (see e.g. p. 264 para 2).

Therefore, the reference is deemed to anticipate the instant claims above.

In the alternative, even if the claimed extract composition is not identical to the referenced extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced extract composition is likely to inherently possess the same characteristics of the claimed extract composition, particularly in view of the similar characteristics which they have been shown to share. Please note that the inevitable ingestion of the food product taught by Fagbemi would intrinsically treat Inflammatory Bowel Disease with respect to preventing Inflammatory Bowel Disease. As drafted, claims drawn to a method of treating Inflammatory Bowel Disease read on preventing Inflammatory Bowel Disease in a subject, as administering therapeutic compositions for Inflammatory Bowel Disease would intrinsically prevent the condition in any subject who does not have Inflammatory Bowel Disease. If necessary, the adjustment of particular conventional working conditions (e.g. adding a wash step using ethanol) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Thus, the claimed extract composition

Art Unit: 1655

would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the art rejection above, please note that “the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” In *re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In *re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Also with respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art



Art Unit: 1655

composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

### ***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie Alonis whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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